

Application No. 10/762,439  
Amendment dated September 28, 2007  
Reply to Office Action of May 30, 2007

Docket No.: CDSJ-P01-041

### REMARKS

Claims 1-21 constitute the pending claims in the present application. The Examiner has withdrawn claims 4-9 and 11-13. Claims 1-3, 10, and 14-21 have been rejected under 35 U.S.C. 103. Claims 15 and 19 have been canceled. Claims 1, 2, 14 and 18 have been amended in response to the Examiner's rejection. Support for these amendments can be found, for example, in the specification on p. 6, lines 17-23, p. 7, lines 22-25, p. 9, lines 27-32, p. 10, lines 1-22, p. 17, lines 14-17, and p. 25, lines 6-12. Applicants assert that these amendments are fully supported by the specification and add no new matter.

Applicants respectfully request reconsideration in view of the foregoing amendments and following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Rejection based on 35 U.S.C. 103(a). Claims 1-3, 10, and 14-17 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al. (U.S. Patent No. 5,378,475) ("Smith"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Pursuant to MPEP 2142:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure.

*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Smith discloses the method and device for treating a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect wherein, the device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. The first coating layer covers the inner core, however, at least a small portion of the inner core is not covered with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core. (abstract, U.S. 5,378,475).

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Conversely, the pending claims recite a sustained release drug delivery device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising: (i) an inner drug core comprising a adrenergic agent *and matrix material wherein said adrenergic agent is admixed in the matrix material to inhibit or prevent decomposition of the adrenergic agent*. Smith does not disclose nor suggest an inner core containing *a matrix material that is admixed* with the active agent in addition to the first impermeable polymer coating. In fact, Smith defines the inner core or reservoir as containing "an agent effective in obtaining a desired effect." (col. 4, lines 20-21, U.S. 5,378,475). Smith is silent with regard to *anything* further, let alone a matrix material, in the inner core or reservoir.

The Examiner contends that a polymer matrix would have been obvious to one skilled in the art given the materials taught by Smith in the following passage: "naturally occurring or synthetic materials that are biologically compatible with body fluids and eye tissues and essentially insoluble in body fluids which the material will come in contact include,...polyvinyl acetate..." (Col. 6, lines 41-66, U.S. 5,378,475). Applicants assert that this passage is directed to materials suitable for fabricating the first or second coating layer of the described invention as evidenced by the preceding and following paragraphs, not for disclosing a matrix material *admixed with an effective agent* of the inner core. (Col. 6, lines 30-40, Col. 6, line 67 to Col. 7, line 9, U.S. 5,378,475).

In light of the above arguments, Applicants submit that Smith does not teach all of the claimed features of the present application. Accordingly, Applicants request that the Examiner withdraw the rejection.

Rejection based on 35 U.S.C. 103(a). Claims 1-3, 10, and 14-17 are rejected under 35 U.S.C. 103(a) as being obvious over Smith et al. (U.S. Patent No. 5,378,475) ("Smith") in view of Wong et al. (U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Wong discloses controlled release devices which have a core comprising a drug. In addition, a polymeric outer layer which is substantially impermeable to the entrance of an environmental fluid and substantially impermeable to the release of the drug during a delivery period covers the core. Drug release is effected through an orifice in the outer layer. (abstract,

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U.S. 6,331,313). Wong does not teach a device that includes a matrix material that is admixed with the drug to inhibit or prevent decomposition, as recited in the pending claims.

As discussed above, Smith does not teach an inner core comprising an adrenergic agent admixed with a matrix material. In fact, both Smith and Wong are silent with regard to any additional material within the inner core aside from an active agent. Therefore, Applicants submit that Smith in view of Wong does not teach or suggest all of the claimed features of the subject application. Accordingly, Applicants request that the Examiner withdraw the rejection.

Rejection based on 35 U.S.C. 103(a). Claims 18-21 are rejected under 35 U.S.C. 103(a) as being obvious over Chen et al. (U.S. Patent No. 5,902,598) ("Chen"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Chen discloses a method and device for sustained drug release that includes an inner core reservoir of effective agent, a first coating layer permeable to the passage of the effective agent, a second impermeable coating layer, and a third coating layer permeable to the passage of the effective agent. (abstract, U.S. 5,902,598). Chen does not teach a device that includes a matrix material that is admixed with the effective agent to inhibit or prevent decomposition. In fact, Chen is silent with regard to any substance contained in the inner core other than the effective agent.

The Examiner alleges that an inner drug core admixed with a polymer matrix would have been obvious given the materials taught by Chen as evidenced from the passage, "naturally occurring or synthetic materials that are biologically compatible with body fluids and eye tissues and essentially insoluble in body fluids which the material will come in contact include...". (Col. 7, lines 1-14, U.S. 5,902,598). Applicants assert that this passage refers to materials suitable for a polymeric layer used to *cover* the inner core of the disclosed invention and do not make obvious the inclusion of a matrix material *admixed with the effective agent* as taught in the present application.

In light of the above arguments, Applicants submit that Chen does not teach each and every limitation of the pending claims. Accordingly, Applicants request that the Examiner withdraw the rejection.

Rejection based on 35 U.S.C. 103(a). Claims 18-21 are rejected under 35 U.S.C. 103(a) as being obvious over Chen et al. (U.S. Patent No. 5,902,598) ("Chen") in view of Wong et al.

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(U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

As discussed above, while both Chen and Wong disclose a device that includes an inner core containing an effective agent, neither discloses a matrix material that is admixed with the drug to inhibit or prevent decomposition, as recited in the pending claims. In fact, both patents are silent with regard to any additional material within the inner core aside from the active agent. Therefore, Applicants submit that Chen in view of Wong does not teach or suggest all of the claimed features of the subject application. Accordingly, Applicants request that the Examiner withdraw the rejection.

Co-pending applications. Lastly, Applicants, in accordance with the on-going duty of disclosure, would like to direct the Examiner's attention to a Non-Final Office Action issued on May 30, 2007 in co-pending U.S. application 10/762,421.

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617.951.7000. A one-month petition for extension of time and authorization of the prescribed fee are being filed herewith. Please charge any further fees due or credit any overpayments to our Deposit Account No. 18-1945, under Order No. CDSI-P01-041 from which the undersigned is authorized to draw.

Dated: September 28, 2007

Respectfully submitted,

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